



CHINA
TOP SECTOR LIFE SCIENCES
OPPORTUNITIES FOR DUTCH COMPANIES



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OPPORTUNITIES FOR DUTCH COMPANIES

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CONTENTS

1. Introduction	5
2. Overview of the Chinese healthcare	7
2.1 General needs of the Chinese healthcare market	7
2.2 Current healthcare situation	8
3. Major drivers from the Chinese government	11
3.1 Health reform	11
3.2 12 th Five-Year Plan (2011-2015)	12
3.3 Main strategic agenda's on biomedical R&D	13
3.4 Major life science clusters	14
4. Overview of main Chinese healthcare sectors	17
4.1 Market for medical devices	17
4.2 Pharmaceutical and biotech sector	20
4.3 Healthcare services sector	23
5. Practical matters	28
5.1 Market access	28
5.2 Intellectual Property Rights (IPR)	28
5.3 Procurement	29
5.4 Catalogue for Foreign Investment	30
5.5 Relevant Chinese organizations	32
6. Opportunities, challenges of the Chinese healthcare market	35
6.1 Summary of opportunities and challenges	35
6.2 Entering the Chinese market	37
6.3 Support by the Dutch government	37
7. Regional opportunities	39

1.

INTRODUCTION

China's healthcare industry is undergoing significant growth and development, at a rate far exceeding that of the nation's annual GDP. The total output of the Chinese medical industry was 1.24 trillion RMB in 2010, with an annual growth rate of 23% since 2005. In a country with over 1.3 billion people and impressive GDP growth rates, vast financial resources are invested to improve the healthcare services for an ageing population. The proportion of wealthy inhabitants is increasing, and the improved living standards lead to higher awareness and demand for quality healthcare.

To meet the increasing demands of this changing society, the Chinese government started a health reform in 2009, which already received EUR 140 billion in investments. The reform aims to provide every Chinese people with accessible, affordable and quality basic medical service in 2020. Nevertheless, the total health expenditure only accounts for 5.1% of GDP (2011), which is relatively low compared to most developed countries. The total healthcare expenditure is expected to increase to 6.7% of GDP in 2015.

Improved living standards lead to higher awareness and demand for quality healthcare

Five key fields are defined for the short-term plan of the healthcare reform, which include a basic medical insurance system, a national essential drug scheme, a grass root medical service scheme, a basic public health service, and reform of public hospitals. All fields create huge opportunities for the Chinese medical industry. Even for niche products, China can be a huge market because of the higher number of patients or users and the larger volumes.

Second tier cities may be more open to foreign business

Driven by these developments, the Chinese Life Sciences & Health industry is expected to continue its impressive growth and become the 2nd largest LSH market in the world before 2020. When considering entering the Chinese market, one needs to keep in mind that realities differ greatly across the vast country. Advanced urban areas such as Beijing, Shanghai and Guangzhou offer very different opportunities than poor areas in provinces such as Shanxi, Gansu or Henan. In between are China's second tier cities, which are currently emerging economically and socially. These second tier cities may be more open to foreign business as they are competing to outperform others.

This report starts with a general overview of the Chinese healthcare market, including the current developments of the market and the healthcare situation. Followed by a summary of the healthcare reforms of the Chinese government and an overview of the major life sciences clusters in China. After that separate healthcare sub sectors are highlighted, such as the market for medical devices, pharmaceuticals, biomedical drugs and the healthcare services, such as hospital building, health information systems, medical rehabilitation and elderly care. Chapter 5 gives practical information on the field of market access, government procurement, regulations for foreign investment, and a list of relevant Chinese organisations. Chapter 6 provides information about support from the Dutch government and the final chapter shows opportunities in several fast growing regions in China.

2.

OVERVIEW OF CHINESE HEALTHCARE

2.1 GENERAL NEEDS OF THE CHINESE HEALTHCARE MARKET

The Chinese healthcare system and market is undergoing rapid changes and growth. As the country with the largest population in the world, it is a huge challenge for China to organise and manage the healthcare system in an optimal and sustainable way. Effective healthcare policies and insurance systems are needed to provide accessible healthcare to everyone, especially in the face of new challenges such as the high prevalence of NCDs and the ageing society. At the same time, healthcare costs need to be constrained in order to remain feasible and affordable in the future. Therefore, China is looking for new, innovative medical products, strengthening of the primary care institutions and solutions such as e-health. In the process of developing better organisation and management of the healthcare system, the Chinese government has been seeking cooperation with western countries to learn from their expertise and best practices.

Most county and township health centers need to be provided with better equipment

Because of the large differences between regions and between cities, counties and townships, the Chinese healthcare market is highly influenced by the local government policies and resources. The large city hospitals have sufficient funding and income to purchase high-end, expensive products from western countries. These hospitals often use the possession of famous brand products to promote themselves and to attract patients. On the other hand, only basic equipment is available in most county and township health centers. These cheaper, low-end products are usually produced by domestic manufacturers. The number of county and village health centers has significantly increased during the health reform (see Chapter 3), and many existing ones need to be provided with better equipment. Therefore, the rural market is large despite the lower product prizes. To enhance the performance and capacity of rural health centers and clinics, low-cost, robust, and versatile medical devices are needed. Due to the lack of trained hospital staff to operate the devices, medical equipment for this market should be user-friendly and automated.

2.2 CURRENT HEALTHCARE SITUATION

Chronic diseases

According to the World Bank, non-communicable diseases (NCDs) are the number one health threat in China, causing 83% of the 10.3 million annual deaths and almost 70% of total disease burden¹. The NCDs with highest mortality are cardiovascular diseases (CVD), cancer, diabetes, and respiratory diseases (Figure 1). Annually, around 3.7 million Chinese die before they reach their 60's as a consequence of these NCDs.

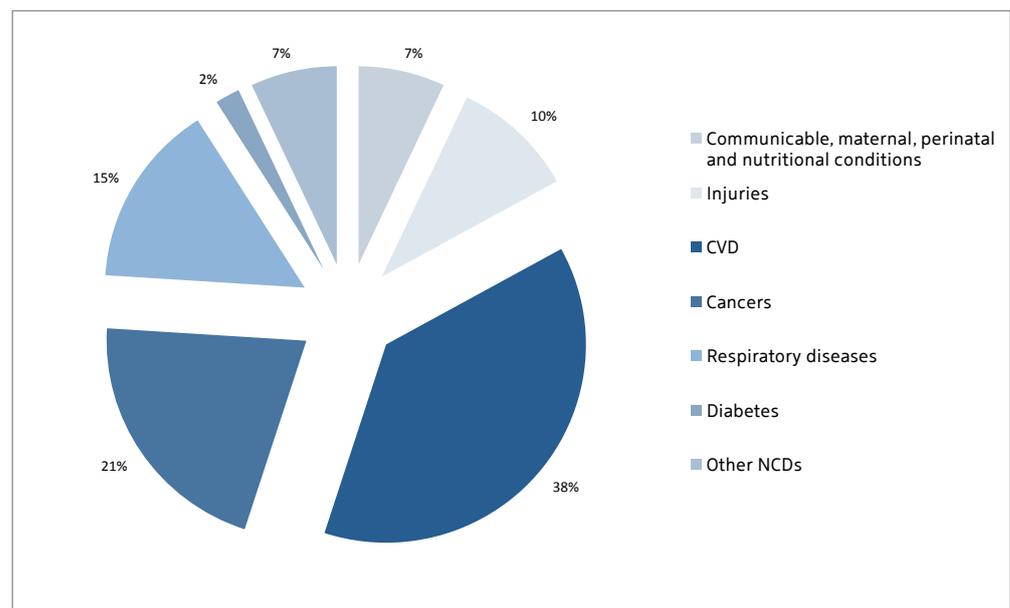


Figure 1. Proportional mortality (% of total deaths in China, all ages, 2011)²

The prevalence of NCDs is still rising and is expected to increase by almost 50% until 2030, resulting in a high burden for the healthcare system (Figure 2). As a result of urbanization and industrialization, NCD-related risk factors have become widely spread. Currently, over 50% of Chinese males consume tobacco, 200 million people have high blood pressure, 90 million suffer from diabetes, and approximately 6% of the population is obese (BMI > 30)³. It is predicted that by 2030, 3.5 million people will die as a result of smoking, which is over 43% of all tobacco-related deaths worldwide. Therefore, the Chinese government is developing policy measures to reduce the prevalence of these risk factors and to control the rapidly increasing disease burden of NCDs.

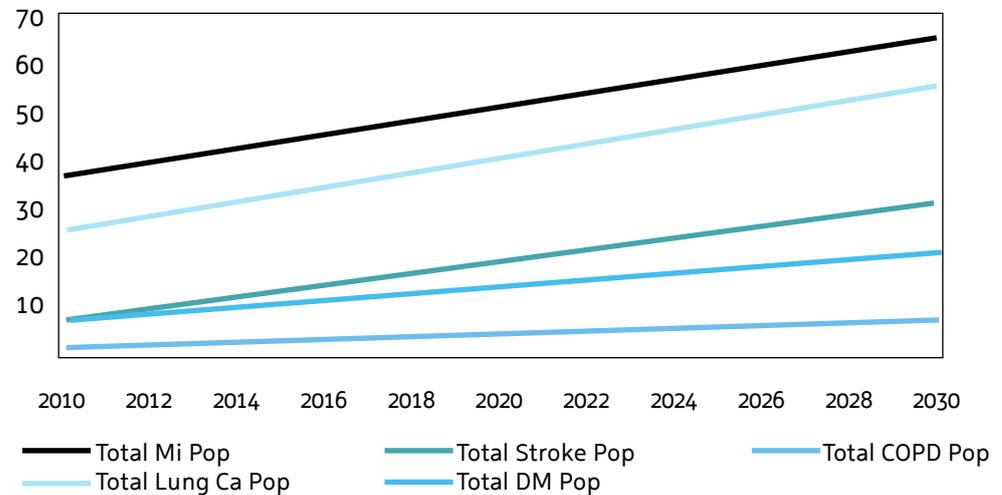


Figure 2. Projected number of NCD cases (people aged 40 years or over)⁴.

MI: myocardial infarction, DM: diabetes mellitus, COPD: chronic obstructive pulmonary disease.

Ageing

The average life expectancy of the Chinese population has increased to 74,8 years. The government aims to increase this number by another year before 2015. The rapidly ageing population is becoming a significant problem for the Chinese society. It is estimated that in 2020, about 17% of the population or 248 million will have reached the retirement age of 60 years. By 2050, this will be 30% of the population. In the most developed cities such as Shanghai, the percentage of 60+ population already hits 23%.

The consequences of the ageing population in China are augmented by the single child policy. A problematic 4-2-1 model has developed over the years, in which two working parents with one child are responsible for four grandparents. The government will have to find a solution to provide elderly care for those who do not have children or sufficient savings to provide for themselves. The China National Committee on Ageing is therefore currently seeking solutions for the challenge of the ageing society, whereas local governments of 1st tier cities such as Beijing and Shanghai as well as 2nd tier cities are experimenting with privately driven 'senior living' solutions. There seems to be a great lack of knowledge and expertise about proper elderly care concepts. The Netherlands is seen as a good example because of its long history of elderly care homes and long-term care insurance.

Infectious diseases

Although infectious diseases are not a major cause of deaths in China anymore, they still contribute significantly to the disease burden both directly and indirectly, and still require a massive effort of the public health authorities to prevent and control them. Especially in rural areas and smaller township hospitals with poorer facilities, local outbreaks of infectious diseases can become a burden for public health. Even in cities and high-end hospitals, infectious diseases can be a serious threat as the population density is usually high. They also contribute to the NCD disease burden indirectly since certain viral infections can lead to the development of NCDs such as liver and cervix cancer.

Infectious diseases can be a serious threat as the population density is high

The infectious diseases with highest mortality rates in China are TB, AIDS, hepatitis B, rabies, and hemorrhagic fever. 39 infectious diseases are currently classified as notifiable in China. All hospitals, health centers and clinics are obligated to report suspected and confirmed cases of notifiable diseases to the Center of Disease Control (CDC) of the county in which they are located. The county CDCs then transfer the information to the national CDC through the National Infectious Diseases Monitoring Information System Database. The central CDC is responsible for the collection and analysis of registered data.

3. MAJOR DRIVERS FROM THE CHINESE GOVERNMENT

3.1 HEALTH REFORM

A major driver for the medical market in China is the latest round of national healthcare reform. It was launched in 2009 and aims to provide nation-wide accessible, affordable and high-quality basic medical service by 2020. Between 2009 and 2011, 1134 billion RMB (EUR 140 billion) has been invested in the reform, which exceeded the budgeted 850 billion RMB.

The total health expenditure was 2.4 trillion RMB (EUR 300 billion) in 2011, which is an over twofold increase compared to 2006. The government health expenditure has increased to 30%, whereas social insurance covers 34.5% and 'out-of-pocket' payments by patients and their families now stand for 35% of all health expenditure. Although still on the high side, the decrease of out-of-pocket expenditure is a huge improvement compared to the levels in the early '00s (60%). Overall, there is still room for growth as the per capita expenditure is now 1806 RMB/capita (220 euro), very low compared to the Netherlands (over 5100 euro/capita).

The health reform aims to improve the healthcare quality by achieving the following goals:

- *Universal coverage of basic insurance.* Currently, over 90% (1.26 billion) of the Chinese population takes part in three basic health insurance programs. 66% is insured in the New Rural Cooperative Medical Scheme (NRCMS), 19% in the Basic Medical Insurance Scheme for Urban Employees (BMISUE), and 15% in the BMIS for Urban Residents (BMISUR). The Ministry of Health (MoH) aims to provide basic insurance to the entire population. The average coverage of healthcare costs is around 60% in rural areas and 75% in cities. Therefore, medical costs for complicated treatments and NCDs such as cancer or other chronic diseases can become unaffordable. Many people save money throughout their life to cover for future healthcare costs. The goal of MoH is to increase rural area coverage to 70%. The Ministry of Human Resources & Social Security (MOHRSS) also plays a major role in the insurance reform, since it is responsible for the implementation of BMISUE and BMISUR.
- *Implementation of national 'Essential Drug' system.* The National Development and Reform Commission (NDRC) has composed a list of 'essential drugs' with fixed prizes, which should be prescribed by doctors and are

reimbursed. This policy is now implemented in over half of the ‘grass roots’ county and township health centers. As a result, the cost of included essential drugs decreased by 30% in 2010, which contributes to higher accessibility of medicines. However, still many other drugs apart from those on the national list can be sold through hospitals.

- *Accessible ‘grass roots’ healthcare and reform of public hospitals.* In China the hospitals are ranked in 3 levels, based on their quality and scope of services. The large majority of the in total 13.503 hospitals (2011) are level 1 (lowest) and level 2. There are 1399 level 3 hospitals. To improve this situation, 2000 county level hospitals will be built or renewed. The cooperation between larger urban hospitals and rural health centers will also be stimulated. One of the key issues is to change the current incentive for doctors in hospitals to increase their low salaries by prescribing unnecessary diagnostics, drugs or therapies.

One of the key issues is to change the current incentive for doctors to increase their low salaries

- *Improvement of public health.* Since the outbreak of SARS, public health surveillance systems have been greatly improved. The prevalence of major infectious diseases is controlled by vaccination programs. However, infectious diseases still cause serious problems for public health in rural areas. The government currently emphasizes on prevention of infectious diseases and mainly invests in regions in central and west-China with fewer financial resources.

3.2 12TH FIVE-YEAR PLAN (2011-2015)

The Health Reform will be continued under the 12th Five-Year Plan, with a focus on deepening the public hospital reform, implement the Essential Drugs system in the public hospitals, and deepen the coverage of the basic insurance. Furthermore, the biotechnology sector is selected as one of the 7 ‘Strategic Emerging Industries’ in the 12th Five-Year Plan. Between 2011 and 2015, the Chinese government will spend 20 billion RMB (EUR 2.5 billion) on innovative medicine, the cultivation of new varieties of genetically modified organisms and on the prevention and control of viral hepatitis and other infectious diseases, according to Ma Hongjian, deputy director of the China National Center for Biotechnology Development⁵. China actively promotes technological development by large investments and favourable policies in designated ‘bio-medical development zones’, of which there are 22 countrywide.

In the Chinese biotechnology industry, there is a lack of breakthrough research and innovative ideas. The Chinese government and industry therefore welcome strategic partnerships with foreign organisations to attract more cutting-edge technology and innovative products. In the ambition to become a knowledge-based economy, China also stimulates innovation and translational research by domestic companies and research institutes. One of the measures is to attract talented Chinese scientists who acquired a PhD degree abroad, by providing them with attractive funds for research equipment and staff. In the “National 1000 Talents Plan”, over 2.000 selected senior scientists with western educational background have returned to China during the last three years.

3.3 MAIN STRATEGIC AGENDA'S ON BIOMEDICAL R&D

The Chinese government has determined scientific agendas, which indicate the Chinese R&D ambitions and focus direction for innovative technologies and products. Government funds, which are related to these scientific programs, support numerous research projects by both academia and companies. The most relevant state programs for fundamental and translational biomedical research are currently the ‘National Medium- and Long-Term Program for Science and Technology Development’ (2006-2020)⁶, the ‘12th Five-Year Plan for Science and Technology Development’, the ‘12th Five-Year Plan for Biotechnology Development’, and the ‘12th Five-Year Plan of the Medical Device Industry’. These development plans are drafted by the National Development & Reform Commission (NDRC) and MoST. General goals include an annual growth for the biotechnology sector of at least 15%, the improvement of independent innovation capacity of the industry, the increase of R&D investments, R&D human capital, scientific citations, and registered patents.

The main focus areas and priority themes in healthcare and biotechnology of the state science and technology development programs are summarized below.

Early diagnosis, prevention and early intervention of major diseases (cardiovascular diseases, cerebrovascular diseases and cancer), to improve the disease control and prevent the need for therapies.

- Control, prevention, diagnosis and rehabilitation technologies for common diseases in rural areas. Focus on small and mobile medical service equipment, remote diagnosis and service systems.
- Prevention and control of infectious diseases such as AIDS, hepatitis and tuberculosis.

- Development of effective contraception products, birth control technology, non-invasive effective birth defect screening, diagnosis and treatment of genetic disorders.
- Development and implementation of e-health and telemedicine systems (e.g. cloud computing and Internet of Things) to provide new services such as remote and mobile healthcare.
- Heritage and innovation of TCM.
- Research and development in the field of:
 - Pathogenesis and prevention of chronic NCDs, infectious and immunological diseases, and age-related diseases
 - Drug target discovery
 - Genetic manipulation
 - Advanced therapeutic and diagnostic medical equipment
 - Digital medical technology
 - Personalized medical technology and equipment
 - Nano biomedicine release systems
 - Tissue engineering technology
 - Tissue regeneration and new biomedical materials

To support research projects, which contribute to the state science and technology development goals, several government funds provide financial resources to Chinese scientists, research institutes and high-tech companies. The most important funds are the National Natural Science Foundation, National High Technology Program (863 Program), National Basic Research Program (973 Program), and Key Technologies Program.

3.4 MAJOR LIFE SCIENCES CLUSTERS

To achieve the goals as stated in the national programs and agenda's, increased government investments are used to intensify research in focal biotechnology areas. Availability of high-quality human resources will be improved and more cooperation with foreign companies and research institutes is stimulated. Also, the Chinese government is currently investing vast amounts in the development of science parks, innovation centers and incubators. The most important life science clusters in China are listed below.

Shanghai ZhangJiang Hightech Park is a state level innovation park and has become the center for pharmaceutical R&D of China. Many multinationals (e.g. Pfizer, GSK, Eli-Lily, DSM, Novartis, Roche, and Abbott) have established their R&D center within ZhangJiang due to the presence of excellent

research institutes (e.g. Shanghai Institute of Materia Medica, Chinese Academy of Sciences (CAS), Fudan University, ShuGuang academic hospital).

Beijing Zhongguancun (ZGC) Life Science Park has been developed by the Beijing Municipal Government since 2000. It is part of the ZGC Science and Technology Park and aims to be a national innovation base for life sciences, new medicines, and advanced pharmaceuticals.

Taizhou China Medical City (CMC) has been growing rapidly since its start-up in 2005 and covers an area of nearly 30 km². It is the only state-level pharmaceutical and biomedical high-tech industrial park in China. In addition to office and production facilities, university medical faculties and a hospital, a branch office of the Jiangsu provincial SFDA is also situated in the CMC.

Suzhou BioBay. Since the establishment in 2006, Suzhou BioBay has attracted both domestic and international pharmaceutical and medical companies, which focus on drug discovery, diagnostic medical devices, and nanomaterials. 19 top scientists who are included in the “National 1000 Talents Plan” have started their own companies in BioBay. The Suzhou Institute of Nano-tech and Nano-bionics and CAS are also present in BioBay, with which research platforms have been set up.

Wuhan National Bio industry park (BIOLAKE) is located in Wuhan East Lake National Innovation Demonstration Zone. Biolake was established in 2008 and is made up of Innovation Park, Biomedical Park, Bio-agriculture Park, Medical Instrument Park, Bio-energy Park and Sino-Singapore (Wuhan) Biotech Park. Currently, over 300 companies signed a cooperation agreement or MOU with Biolake and over 100 enterprises have already moved into the park. Biolake aims to host more than 1000 biotech enterprises and achieve a total revenue of RMB 200 billion by 2020.

Shenzhen Hi-Tech Industrial Park (SHIP) was founded in 1996 and one of China’s five state-level high-tech parks. SHIP provides integrated services to enterprises, researchers and investors. It has been selected by national authorities as the country’s Export Base of Hi-Tech Products, named as the preferred APEC (Asia-Pacific Economic Cooperation) Hi-Tech Industrial Park, and received the designations of Advanced State-level Hi-Tech Industry Area and National Software Industry Base. In 2008, its output of hi-tech products was over 213 billion RMB (EUR 27 billion).

Guangzhou International Bio-Tech Island was opened in 2011 to the global biotech sector. Agreements were signed on 30 state-of-the-art bio-

tech projects and supporting projects. These projects will involve a collective investment over 2.5 billion RMB and focus on various high-tech sectors, including marine biology, modernization of traditional Chinese medicine, stem cell research, regenerative medicine, bio-energy, and bio-contract service outsourcing⁷.

4.

OVERVIEW OF MAIN CHINESE HEALTHCARE SECTORS

4.1 MARKET FOR MEDICAL DEVICES

Even after the significant growth in the past decade, the medical device industry in China has a large growth potential. The market is still relatively undeveloped considering the large population. The sales volume for medical devices reached total revenues of 135.4 billion CNY (21 billion USD) in 2011⁸ (Figure 1). With double-digit annual growth rates of the medical device industry, China is expected to become the 2nd largest market before 2020⁹.

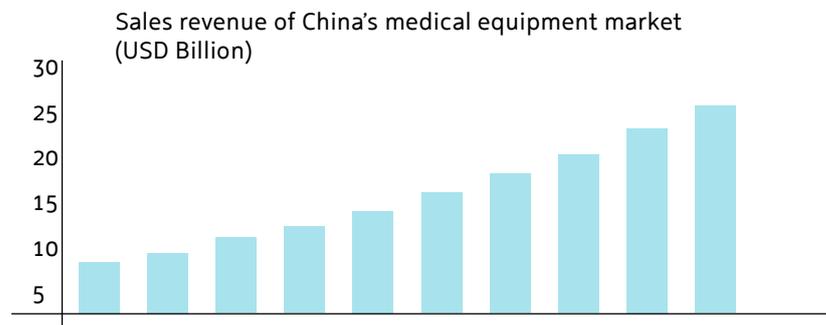


Figure 1. Recent and expected growth of the Chinese medical devices sector¹⁰

Per capita, the medical device market size in China is currently only around EUR 12 per capita, compared to EUR 250 in the US and EUR 170 in Germany. The continuous growth of this industry is also illustrated by the growing number of both Chinese and western venture capital companies which invest in promising projects for the Chinese market. In the first three quarters of 2012 alone, Chinese VC/PE companies have been involved in 24 investment projects on medical technology¹¹.

The Chinese domestic medical device industry is highly fragmented. Over 80% of the approximately 14.000 Chinese medical device manufactures are small and middle-sized enterprises, mainly focusing on the lower-end medical device market. The regions Beijing, Shanghai, Guangdong, Jiangsu and Shandong have the highest concentration of domestic manufacturers. China's export value for medical devices in 2011 was approximately EUR 12 billion. For advanced and high-end medical equipment such as x-ray, surgical equipment and colour ultrasound diagnostic equipment, China still relies heavily on foreign manufacturers. About half of the medical device market consists of these imported, high-end products. In 2011, the imported devices had a total value of approximately EUR 8.5 billion. Of all imported prod-

ucts, almost 40% originates from the EU, 30% from the USA and 16% from Japan. Within the EU, The Netherlands (3.1%) is the 3rd exporting country to China, after Germany (17,5%) and Sweden (3,7%).

In order to stimulate the innovation capacity of domestic companies and to enhance their competitiveness in the high-end market, the Chinese government plans to support 40-50 innovative high-technology enterprises and to set up 8-10 medical device industry bases before 2015¹².

Opportunities for foreign companies

Whether a product, service, training, or solution package is offered, and whether the application is for high-tech hospitals or small clinics, China is in need for innovative healthcare products and solutions to develop a sustainable healthcare system. These innovative products should possess distinctive characteristics in order to have added value and competitiveness in this challenging market, which is dominated by large multinationals. It will be hard for foreign companies to compete in the low-end segments of the market since domestic companies will usually have more competitive prices.

Approximately 80% of all high-end medical devices in China are manufactured by foreign companies. Both healthcare institutions and patients are highly interested in technology from western countries and are willing to pay more for international brand products. In contrast, domestic companies generally focus on the lower-end products. To strengthen the competitiveness of Chinese companies in the high-end market, the government aims to stimulate the domestic innovation capacity. However, translational research and the development of innovative products in China are still in their infancy. Chinese companies are therefore keen on investing in promising projects of western partners, R&D collaboration, or technology transfer.

Chinese companies are continuously seeking new products which are already approved in the foreign markets

Chinese companies are continuously seeking new products and promising technologies, since their product pipelines are often not sufficiently filled by the output of research activities. These companies are preferably looking for products, which are already approved in the foreign markets or are in clinical trial phase II and III with a concrete outlook on marketable products in the near future.

Chinese companies are generally open for several collaboration options such as joint R&D with foreign companies and research institutes on products

which are still in developmental stages, or acting as the local representative and distributor. Another option for especially larger Chinese companies is technology transfer, since they have sufficient financial resources but lack translational R&D capacity.

Case study: Applikon Biotechnology BV

This global leader in innovative bioreactor systems will be opening a manufacturing plant for stainless steel bioreactor systems in Science City, Guangzhou Development Zone in China. When completed, the plant will manufacture bioreactor systems, supplying customers primarily in China and the Asia-Pacific region. The 3000m² facility is expected to begin production in April 2013.

The production facility is a joint venture with a Chinese distributor where Applikon holds 60% of the shares. The Managing Director of Applikon is the chairman of the board and the Dutch General manager has lived in China for six year and speaks Chinese. It has taken a long time to find this person. Applikon interviewed a large number of candidates and found it was virtually impossible to find a Dutch person who lived in China, had a technical background and would fit in our financial profile. The company is now in the process of finding the right (technical) Chinese employees to get the operation started.

Negotiations started 24 months ago, getting the official business license took approximately one year. A major point during negotiations with their business partner was the ownership of current and future IPR. Applikon did not want to share the IPR directly related to the core business. They hired a Dutch Sinologist specifically to organise the start of the Chinese facility and could not have achieved this project without the frequent communication with China and the detailed knowledge of China and its culture. The company wants to get a high-tech license from the Chinese government, since it offers significant tax benefits. The procedure to get this license is not very clear and it might take a few years to get this status. The Dutch embassy and the consulate were very helpful to get insight in the procedures and arranging the contacts with the right Chinese officials.

What Applikon learned in the past years is that you need to be well prepared when you want to achieve something in China and that patience is key. They have great expectations for the success of their Chinese operation, since this market is approximately 30% of their global turnover and they expect this to grow. The company is convinced that a local facility will improve the relation with the Chinese customers. Critical success factors are also shorter delivery times for the local market and faster after sales service.

4.2 PHARMACEUTICAL AND BIOTECH SECTOR

With the overall economic growth as well as healthcare spending in China on the rise, it is not surprising that China will become the second largest pharmaceutical market in the world by 2015. The value of the market will reach 62 billion USD in 2015, surpassing India, Brazil and Russia added together by 20 billion (IMS, 2012).

The Chinese pharmaceutical industry is traditionally characterized by a large number of large volume, low value manufacturers of generics and Traditional Chinese Medicine. There are over 5000 pharmaceutical companies, and China's top 3 Big Pharma only has 20% market share whereas in the US it has over 80%. There are no¹³ patented drugs on the global market from Chinese origin, and also in China the patent drug market is dominated by western multinationals.

The Chinese government has taken huge steps in upgrading its regulatory environment

However this landscape is going to change rapidly in the coming years. Major government initiatives are taken aimed at upgrading China's pharmaceutical sector and grow a more innovative and competitive sector.

Firstly, the government has taken huge steps in upgrading its regulatory environment. After several adverse incidents and incidents of corruption in the recent past harmed the reputation of Chinese pharmaceuticals as well as its regulator, the SFDA, China has taken convincing steps to revamp its reputation. The SFDA is tackling corruption, improving its professional standards and has developed many new regulations, which make China's regulatory environment more and more compatible with international standards. For example, in 2011 the SFDA launched a new GMP standard, which should greatly improve quality control and management systems, and was widely received as being on-level with international standards. Also standards for clinical trials are being improved. However, recent incidents involving unsafe drugs are still stirring public attention, and counterfeit drugs on the domestic as well as on the global market which are made in China are still rampant.

Secondly, the Chinese government is pushing for consolidation of the pharmaceutical sector. The Ministry of Industry and Information Technology as well as the Ministry of Commerce have issued policies aimed at restructuring the pharmaceutical industry as well as the distribution sector. China's Big Pharma (generic giants such as Sinopharm, China Resources Pharma-

ceutical Group, Shanghai Pharma, Harbin Pharmaceutical Group and others) are active in bigger and smaller domestic acquisitions of pharmaceutical companies, aiming on the one hand to increase their nationwide coverage for distribution, on the other hand also to grab a share of innovative companies with new products in the pipeline. The aim is clearly to build a more innovation driven and less imitation driven pharmaceutical industry.

The Chinese industry is aware that it needs foreign technology and expertise to make further progress

Thirdly, China is boosting its R&D. The bio-industry is marked as one of the 7 strategic industries according to the State Council. During the 12th Five-Year Plan period (2011-2015), the Chinese government will spend 20 billion RMB on innovative medicine, on the cultivation of new varieties of genetically modified organisms and on the prevention and control of viral hepatitis and other infectious diseases. Within the next Five-Year Plan-period, 30 innovative drugs, 150 diagnostic reagents, 40 new biological drugs are supposed to be developed, and 10 clinical trials of new drugs to be initiated. To encourage innovative drug development, selected innovative drugs will be included on the Essential Drug List so they will be reimbursed. It must be noted that there is historical evidence for successful government-driven development of pharmaceutical industry: in countries like Switzerland, Israel, Germany and the US, the pharmaceutical industry has benefited from heavy R&D spending by their governments.¹⁴

Case study: Hecolin

End October 2012, the first Hepatitis E vaccine was launched on the Chinese market. The new vaccine, Hecolin, is the product of joined research and investment by Xiamen University National Institute of Diagnostics and Vaccine Development in Infectious Diseases and Xiamen Innovax (subsidiary company of Yangshengtang Group). Hecolin was approved after a phase III clinical trial in 2010 showing that it was highly effective in preventing infection among almost 100.000 healthy participants. The vaccine is based on a genetically modified strain of the bacterium *Escherichia coli* which produces a protein that stimulates the recipient's immune system against Hepatitis E.

Fourthly, the government is fostering a foreign investor friendly business climate. Although the Chinese industry is investing heavily in R&D in order to improve the quality and innovativeness of their products, they are aware

they need foreign technology and expertise to make further progress. Foreign companies on the other hand are well aware that to gain market access to the Chinese market, local presence is needed. Therefore multinationals now seem to aim to join forces with Chinese players by sharing their technology in return for access to the lucrative Chinese market. Joint ventures, mergers and acquisition or joint R&D are all different forms to cooperate. The number of R&D centers by multinationals has increased from 30 to 1600 since 2001. Also multinationals have been active in acquisitions of local innovative companies and are more and more building partnerships with domestic companies.

Finally, R&D cooperation happens the other way around: smaller western innovation-rich biotech companies hungry for cash find cash-rich Chinese Big Pharma, hungry for new products. Therefore licensing and co-development agreements between Chinese companies and smaller foreign research companies are another emerging trend. In many cases, the access to Chinese funds is traded for the market rights for China, while rights for the rest of the world are retained.¹⁵ This model may be of interest to smaller Dutch, innovative biotech companies looking for funds in China.

Policy impact

Apart from the regulatory developments mentioned above, the Essential Medicine Policy has an impact on the pharmaceutical market. On the one hand, the healthcare spending is increasing, implying a growing demand for drugs. On the other hand, MoH policies are put in place, which are meant to reduce the prices of drugs. In 2009 the Essential Drugs List was introduced, currently containing 307 types of basic drugs, which are applicable for reimbursement by the health insurance. For now, the list has only been implemented in the lower level medical services (county, township and village level), but will be expanded to city level hospitals soon. The prices of the listed drugs have been slashed by about 30% due to this policy. Moreover, the health reform aims to take out the incentive for doctors in hospital to attribute to their salary by excessive drugs prescription. The current 'fee-for-service'-system needs to be replaced by performance based payment systems. There are now some 17 pilot cities where new financing schemes are implemented. The success of these new policies remains to be seen, and may depend on whether the government will compensate doctors in their salaries for the loss of income out of drug sales.

Traditional Chinese Medicines (TCM)

To understand the dynamics of the Chinese pharmaceutical industry, one needs to mention the role of TCM. Although the sales of TCM drugs stands for only 8% of the total pharmaceutical market in China, it plays an impor-

tant role in the current healthcare reform. Many major Chinese pharmaceutical companies produce both chemical and TCM drugs. There is a strong government backed drive to gain market access to US and EU market for TCM drugs, and get these products approved as regular medicine by FDA and EMEA standards. On the other hand, some western pharmaceutical companies such as GSK, take a growing interest in the market potential of TCM.

4.3 HEALTHCARE SERVICES SECTOR

The ambitions outlined in the health reform provide opportunities related to all aspects of the healthcare system, to which Dutch business could contribute with knowledge, expertise and technologies.

Hospital build and equipment

China's investment in hospital construction has increased by about 20% annually during the past decade, while the yearly investment in healthcare facilities construction alone is now around USD11 billion per annum. Also during the 12th Five-Year Plan (2011-2015), China will continue to build new hospitals and upgrading the existing ones.

Currently, there are about 13.503 public hospitals, of which 1.399 are level 3 (highest), 6.468 level 2, and 5.636 level 1. The hospitals are ranked based on their function, task, equipment, medical care quality and technical management levels. The grass roots primary healthcare institutions consist of almost 34.000 community health centers, 37.100 township hospitals, over 178.000 township clinics and 664.000 village health stations. The latter two types of health institutions do not offer in-patient services.

According to government plans 2.000 county level hospitals will be built or renewed, to ensure each county will have at least one hospital in compliance with national standards. The reform in existing hospitals focuses on improvement of the internal management structure, quality of the provided medical care, and the reduction of unnecessary treatments and prescriptions to generate income. The cooperation between larger urban hospitals and rural health centers is also stimulated. For example, the skills and experience of medical staff in 'grass roots' health centers can be enhanced by additional training in city hospitals.

These developments result in the need for expertise in optimal design, construction and build of hospitals. Related needed services include the supply and installation of medical equipment, technical assistance, staff training, and management assistance.

It may prove challenging to gain access to public hospital projects as they are publicly tendered. To participate in public tendering, local presence is necessary (see also chapter 5.3). Participating in building projects for private hospitals may prove easier. Private healthcare institutions currently stand for 38% of the total number of institutions, but these are in majority specialized clinics, not general hospitals.

E-health

Just as internet and mobile technology have changed our daily lives, the same may happen in the way healthcare will be provided in the near future. According to one survey, 80% of the Chinese believe it is inevitable that e-health solutions will be widely adopted very soon.¹⁶ E-health may prove to be the answer to the size of the population (especially in remote areas) as well as the lack of access to well-trained doctors in an acceptable travelling distance. Also, it may provide access to reliable information on diseases, while improving preventive healthcare and lowering costs. Wireless communication between patients and clinicians, through internet or smart phone apps, in some cases combined with the usage of home electronic diagnostic devices, may significantly improve the availability of healthcare. E-health or telemedicine can also greatly improve the service quality of smaller clinics by communication and cooperation with specialists in large urban hospitals. Cities such as Beijing, Shanghai, Shenzhen, and Chongqing have already started pilots on IT-based information exchange between hospitals, to establish remote diagnosis, consultation and training, and the exchange of patient electronic health records¹⁷. In 2013, Shanghai aims to realize information integration and exchange between nearly 600 medical centers¹⁸.

However, there are challenges to be overcome as well. Doctors may not always like to adapt their way of working, and healthcare institutions in general may need to change the way they organise themselves. E-health solutions may stimulate a more prevention-focused healthcare while traditionally health institutions are focusing on treatment. Also, technical problems need to be solved, such as interoperability, which enables different systems to exchange data.

China plans furthermore to develop a comprehensive health information system, called '3521' framework:

- The number 3 stands for three administrative layers, which are national, provincial and city level.
- The number 5 stands for five fields, which are public health, medical service, the new rural cooperation medical service, the Essential Drug Scheme, and general management.

- The number 2 stands for two fundamental databases for health record and electronic medical record.
- The number 1 stands for one special network.

Currently, the Chinese Health Information System (HIS) is highly imbalanced among regions and different levels of hospitals. The Chinese government in its National Healthcare Reform Plan vows to set up a 'practical and information sharing' HIS platform, which will integrate the information systems of public health, medical service, medical insurance, pharmaceutical, and financial supervision.

The central government spent 2.7 billion RMB at the end of 2010 to support the HIS development of 420,000 village clinics in central/western China, HIS pilots on grass root level in five provinces, HIS hospital pilots in 16 cities, and the remote medical consultation system. The government is now trying to construct a national platform for rural medical insurance, which can be connected with the provincial platforms.

However, the expenditure on HIS is only about 0.8% of the total health expenditure, which is much lower than the 3-5% in developed countries. The market is expected to further grow with the development of the healthcare reform. Mobile health solutions may also be linked up with the medical personal file, in order to give Chinese customers online access to their medical information anytime of the day.

Hospitals do not have much knowledge about rehabilitation and are looking for models.

Rehabilitation medicine

In 2007 the Chinese health authorities started to promote the development of rehabilitation. From 2010, billions of RMB are invested in construction and equipment, both through the Ministry of Health system as through the China Disabled People Federation (CDPF). Under the CDPF there are two large-scale rehabilitation clinics (in Beijing and Chengdu) and about 230 smaller clinics. The Ministry of Health governs all public hospitals and issued the policy that from 2016 on, all level 2 and 3 hospitals need to have a rehabilitation department, otherwise they will be downgraded. This means the number of hospitals with rehabilitation facilities will increase to almost 7800 in 2015, more than twice the current number.

Hospitals do not have much knowledge about rehabilitation and are looking for models. Currently a pilot project is carried out involving 75 hospitals in 14 different provinces. There is a huge need for training, consultancy on concepts, management and administration, and equipment. Currently, the

allocated government budgets are very high, so the market for rehabilitation equipment is described as a 'sellers' market. In 2012, a G2G project on Sino-Dutch cooperation in rehabilitation medicine was carried out. A Dutch consortium is formed to address a wide range of needs of potential Chinese customers. The consortium is currently identifying local projects which can serve as a model for rehabilitation care.

Case study: Enraf Nonius

As global leader in products for physical therapy and rehabilitation, Enraf Nonius has been active on the Chinese market for a period of more than 10 years, during which it has implemented several projects in China. The company learned that, when you want to be successful in China, you have to focus on a specific field; it requires a dedicated team which builds up the contacts and trust with all stakeholders. The decision making structure is complex and until the moment you have built up a relationship based on trust, the negotiations will be difficult, long-lasting and sometimes very unreasonable. The opportunities in China are immense, but being successful asks for dedication, patience and flexibility.

Elderly care sector

China's ageing society, together with the increasing wealth among elderly Chinese and the decreasing willingness of children to take their parents in their house, causes for high demands in the area of elderly care in China. For now, public homecare is not widely available; on a population of 1.4 billion, there are only 40.000 nursing homes. Several pilots are currently experimenting with informal home- and community care. The private elderly home sector has been expanding, which offers higher quality care, which only the wealthy can afford. Also, so-called 'senior living resorts' have been developed which do not have a specific focus on healthcare services. For elderly without sufficient income, social welfare homes could be an option.

However, these public homes have insufficient capacity with only 18 beds per 1000 elderly aged above 60. The government goal is to provide 30 beds per 1000 elderly by 2015. In addition, public homes are unpopular because of their reputation of low quality service. In conclusion, durable solutions are needed for the increasing numbers of Chinese elderly, such as prevention of chronic diseases, homecare and monitoring devices for longer self-maintenance, healthy ageing solutions, development of public homecare system, and build of new elderly homes with high-quality service.

Since China has little experience in this sector, the government is looking abroad for expertise and considers the Netherlands as one of the countries with the most developed elderly care. One important issue that remains unsolved is the lack of long term care insurance. Finding a solid business model may therefore prove to be challenging.

Training of medical staff

Availability of qualified doctors and nurses is pivotal to improve the quality of healthcare. In the near future, there will be a huge shortage of trained medical staff. The Chinese government is therefore looking for ways to train doctors and nurses. Especially the education of GP's (general practitioners) and nurses in elderly care is emphasized. It is estimated that over 10 million nurses will be needed to meet the demand for elderly care service, whereas currently only 300.000 are available. In addition, training and consultancy on hospital and healthcare system management are also necessary to improve the healthcare organisation. Possible solutions, such as complete GP training or short internships in foreign hospitals, seminars and training programs by western experts in China are supported by the Chinese government.

5.

PRACTICAL MATTERS

5.1 MARKET ACCESS

The State Food and Drug Administration (SFDA), which has been placed under the Ministry of Health (MoH), formulates and supervises policies on the administration of drugs, medical devices, health food, cosmetics, as well as food safety at consumption stage (restaurant, cafeteria, etc.) and supervises their implementation. All medical devices need to be approved by the SFDA in order to access the Chinese market. The approval procedures for market access usually take one and half to two years.

The SFDA is organised into municipality, provincial, and state level bureaus. Medical devices are categorized into three classes, with class I having the lowest and class III the highest risk for the patient. The provincial level SFDA holds the most inspection and approval responsibilities, whereas the municipality level SFDA is only authorized to grant the registration certificate for class I medical devices. Only the state level SFDA can grant the registration certificate and approve clinical trial verifications for class III devices. Information on the classification by SFDA of medical devices is provided on the website of SFDA, www.sfda.gov.cn.

In addition, certain product categories need to acquire the China Compulsory Certification (3C Certification). This certificate is issued by the Chinese Administration of Quality Supervision, Inspection & Quarantine (AQSIQ), which is a ministerial-level department under the State Council. The product categories which need the 3C certification can be found on the website of the Certification and Accreditation Administration¹⁹.

5.2 INTELLECTUAL PROPERTY RIGHTS (IPR)

As medical products rely to a high degree on investment in research and development, protection of intellectual property rights is essential for foreign companies in this field. Therefore, gaining thorough understanding of China's IPR protection system should be an important part of the strategy to enter the Chinese market.

China has established a relatively comprehensive legal system in relation to IPR protection. Under China's existing legal framework, intellectual property on the field of biomedical, pharmaceuticals and medical devices can be protected through patents, trademarks, trade secrets and administrative

protection. However, as in many business sectors in China, violations of IPR are rather common, and are especially severe in the drugs market. In general it is advisable not to only rely on the legal framework, but to take other strategic measures to protect IPR. This can be done by carefully selecting which products and technologies to sell and manufacture in China, choosing reliable Chinese business partners and creating loyalty among Chinese personnel. More information on IPR issues can be obtained from the IPR SME Helpdesk (www.china-iprhelpdesk.eu).

5.3 PROCUREMENT

An important way of entering the Chinese LSH market is taking part in the procurement process of public hospitals. This is however a very complicated and diffuse process, and usually requires close contact with influential stakeholders. Support from a local agent or company is mostly needed, as they can get information about the procurement process long before the tendering is publicly announced.

The procurement of Chinese public hospitals is regulated by the following laws and regulations:

- Government Procurement Law, implemented by the Chinese Ministry of Finance
- Bidding Law, implemented by the National Development and Reform Commission
- Notification on Issues Concerning Government Procurement of Imported Products issued by Ministry of Finance

The amount of government procurement has increased from 100 billion RMB in 2002 to over 1 trillion RMB in 2011, an annual increase of 30%. In 2011, about 80% of all government procurement was done through public tendering. Government procurement can be done either by a central government agency or by the hospital itself. The central procurement can be organised on ministry level, provincial level or city level, according to the category of the medical equipment and pharmaceuticals. Information on government procurement is usually announced on websites, such as www.ccgp.gov.cn and www.chinabidding.com.

5.4 CATALOGUE FOR FOREIGN INVESTMENT

Foreign investment in the Chinese LSH sector is encouraged, restricted or prohibited by the Chinese government, based on the exact products and services involved. This exact category relevant for your business can be found in the “Catalogue for Guidance of Foreign Investment Industries” of the Chinese Ministry of Commerce, of which the latest version was released in December 2011 and can be found on: <http://english.mofcom.gov.cn/article/policyrelease/aaa/201203/20120308027837.html>

Specifically for the LSH sector the Catalogue stipulates the following:

Catalogue of industries in which foreign investment is encouraged:

III (XI) Pharmaceutical Industry

1. Production of new compound drugs or drugs with active ingredients (including drug substance and formulations)
2. Amino acids: production of tryptophan by using zymotechnics process, histidine, and methionine used in feed, etc.
3. Production of new anticarcinogenic drugs, cardiovascular drugs, cerebrovascular drugs, and nervous system drugs
4. Production of new types of drugs employing bioengineering and biotechnology
5. Production of HIV/AIDS vaccines, Hepatitis C vaccines, and contraceptive vaccines, as well as new vaccines for cervical carcinoma, malaria, and hand, foot, and mouth disease
6. Production of biovaccines
7. Development and production of marine drugs
8. Pharmaceutical formulations: production of new formulations and new products employing such new technologies as slow release, controlled release, targeting, and percutaneous absorption
9. Development and production of new excipients
10. Production of special antibacterial drug substance for animals (including antibiotics and chemically synthesized active pharmaceutical ingredients)
11. Production of new products and new formulations of antibacterial drugs, anthelmintics, insecticides and anti-coccidiosis drugs for veterinary use
12. Production of new types of diagnostic reagents

(XVIII) Special-Purpose Equipment Manufacturing Industry

44. Manufacture of key components of medical imaging equipment (including high-field-strength superconducting magnetic resonance imaging

equipment, x-ray computed tomography imaging equipment, digital colour diagnostic ultrasound equipment, etc.)

45. Manufacture of (3D) ultrasonic transducers for medical use

XI. Health, Social Security and Social Welfare Industries

1. Service institutions for the elderly, the disabled and children

Catalogue of industries in which foreign investment is restricted

Medical and Pharmaceutical Products Manufacturing

1. Production of chloramphenicol, penicillin G, jiemycin, gentamycin, dihydrostreptomycin, amikacin, totomycin, oxytetracycline, mydecamycin, leucomycin (stereomycin), ciprofloxacin, norfloxacin and ofloxacin
2. Production of analgin, paracetamol, Vitamin B1, Vitamin B2, Vitamin C, Vitamin E, multiplex vitamin preparations and oral calcium preparations
3. Production of varieties of vaccines which have been incorporated into the national immunity planning
4. Production of active pharmaceutical ingredients (APIs) for anaesthetics and Category I psychotropic drugs (with Chinese parties as the controlling shareholders)
5. Production of blood products

Catalogue of industries in which foreign investment is prohibited

(II) Medical and Pharmaceutical Products Manufacturing Industry

1. Processing of traditional Chinese medicinal materials listed in the Regulations for Protection of Wild Medicinal Resources and the Catalogue of China's Rare, Precious and Endangered Plants under Protection
2. Application of such processing techniques as steaming, stir-frying, moxibustion, and calcination for making small pieces of ready-for-use traditional Chinese medicines; and production of traditional Chinese patent medicine of secret prescriptions.

5.5 RELEVANT CHINESE ORGANISATIONS

General

International Health Exchange and Cooperation Center of Ministry of Health
<http://jjzcg.medicalbridge.com.cn> (only in Chinese)

Under the direct leadership of MoH, this center carries out non-governmental multilateral and bilateral cooperation and exchange projects for MoH, including: provide administrative support to MoH's international health assistance programs; organise exhibitions and international conferences; coordinate overseas training programs and provide consultancy services.

China Center for Pharmaceutical International Exchange
www.ccpie.org/en

A public institution affiliated to the State Drug Administration (SFDA), carries out international exchanges and cooperation through private channels, among enterprises, scientific research institutions, social organisations as well as foreign institutions. CCPIE also sponsors international exhibitions and conferences on pharmacy, medical equipments and health products and carries out relevant technical exchanges and consultancy services.

Chinese Hospital Association
www.cha.org.cn/eng/index.htm

The Chinese Hospital Association (CHA) is a national, trade-oriented, non-profit healthcare organisation, representing more than 1700 hospitals and academic members, 7000 individual members and 22 branches. The organisation is formed voluntarily by all types and all levels of healthcare institutions (excluding rural healthcare stations, clinics, and infirmaries). The purpose of the Chinese Hospital Association is to implement the state's relevant policies and guidelines on health undertakings; and play an active role as an administrative body for trade instruction, and to improve the management level of member institutions, promote sustainable and healthy development of the reform and construction of healthcare institutions.

Chamber of Commerce for Import & Export of Medicines & Health Products
 CCCMHPIE
www.cccmhpie.org.cn

Founded in 1989 and most influential national trade association in China for the promotion of international trade and cooperation in medicinal and health products. Operates directly under the Ministry of Commerce of China and has over 1,800 member companies including most of the major manufacturers and trading companies of pharmaceutical and health products.

*Chinese Academy of Sciences (CAS)**english.cas.cn*

Founded in Beijing in 1949 and leading academic institution and R&D center in natural science, technological science and high-tech innovation in China. CAS has 12 branches, 117 institutes, over 100 national key laboratories and national engineering research centers, and over 50.000 staff members. Hundreds of start-up companies were established as CAS spin-offs. Prominent CAS institutes include the Shanghai Institutes for Biological Sciences (SIBS) and Institute Pasteur in Shanghai.

*Chinese Center for Disease Control and Prevention (China CDC)**www.chinacdc.cn/en/*

National institution under the Ministry of Health in the field of disease control and prevention, public health management and provision of service.

Medical Devices*China Association for Medical Devices Industry (CAMDI)**www.camdi.org/en*

Founded in 1991, an industrial and non-profit association, which consists of companies and individuals engaged in manufacturing, distributing, R&D, and testing of medical devices. CAMDI represents over 4,000 member companies.

Pharmaceutical and biotech*China Pharmaceutical Technology Transformation Center (CPTTC)**www.pharmtec.org.cn*

National organisation, which facilitates technology transfer in the pharmaceutical and biotechnology sector by providing consulting services to the government and companies. Supervised by the SFDA and Ministry of Science and Technology (MoST).

*China National Center for Biotechnology Development (CNCBD)**www.cncbd.org.cn*

Established in 1983, a national center which coordinates and implements the national science and technology program in Biotechnology and Health. The center also functions as a research center for biotechnology policy, a project management and industry consultancy center, and an international information exchange platform for biotechnology and bio-industry.

Chinese Society of Biotechnology (CSBT)

www.biotechchina.org

Founded in 1993, serves as a scientific exchange platform in biotechnology. It promotes scientific collaboration through various academic programs and activities. The society bridges academia with enterprises to accelerate the development and commercialization of biotechnology.

National Institute of Biological Science, Beijing (NIBS)

www.nibs.ac.cn/english

Established in 2003, as part of a government initiative to stimulate national development of science and technology. Its faculties educate future generations of scientists and explore a new model for operating scientific institutions in China.

Sino-EU Chemical Manufacturers Association Biomedical Committee (SEBMC)

www.secma.org.cn/en/sebmc.asp

Biopharmaceutical industry association founded by the Sino-EU Chemical Manufacturers Association (SECMA), representing the interests of biomedical manufacturers. Founded in Hong Kong, the committee is composed of enterprises, universities, and research institutes which engage in new drug R&D, R&D outsourcing, pharmaceutical intermediates, medical devices, and biological materials.

6. OPPORTUNITIES AND CHALLENGES OF THE CHINESE HEALTHCARE MARKET

6.1 SUMMARY OF OPPORTUNITIES AND CHALLENGES

General

1. China invests heavily in improvement of its healthcare system ('universal healthcare by 2020'). Healthcare spending already increased up to 5,1% GDP or about 300 billion EUR in 2011, but at a level of 220 EUR/capita there is certainly room for further growth.
2. NCDs are now responsible for 85% of mortality in China. Therefore China offers a large opportunity for solutions for prevention, treatment as well as disease management of NCDs.
3. China is reported to have infectious diseases under control. However, continuous improvement of surveillance and diagnostic capacity will remain on the agenda and provides opportunity for innovative techniques in this field.
4. China's rapidly ageing population (almost 250 million above 60 by 2020) poses a huge challenge to Chinese authorities. At the same time it may provide opportunities for western partners with knowledge of advance concepts of elderly care.

Medical devices

1. The market for medical devices is expected to be growing at double digits (18-20%) and is one of the fastest growing sectors in the Chinese economy.
2. City hospitals remain the largest market for high-end technology. Over 80% of the high-end medical devices sold in China are of foreign origin.
3. The strengthening of primary healthcare institutions on county and community level opens a large potential market for easy-to-use, lower to middle cost medical devices.

Pharma and biotech

1. The central government invests heavily in China's innovative new drug development. Multinationals partner up with domestic pharma in their R&D endeavours. In this way, technology transfer is traded for market access.
2. Western small innovative biotech companies looking for funds to develop their technology will be able to find Chinese pharmaceutical companies with plenty of cash, and an increasing level of knowledge and expertise to build fruitful cooperation. The price to be paid might be

that the license for the Chinese market is handed to the Chinese partner, while retaining the rights for the rest of the world.

Health services

1. The wave of building new hospitals and village clinics that was initiated by the health reform will continue during the 12th Five-Year period. New or upgraded hospital building projects are especially to be expected in 2nd tier cities as well as in county level hospitals. A huge challenge is to gain access to projects for public hospitals through the public tendering procedures. It may prove much easier to obtain a project for a private hospital, for which the number is currently on the rise.
2. Additional to hospital building and design, there is a huge need for training of doctors and nurses, as well as other specialized hospital staff. Also there is need for improvement of management and administration of health institutions, requiring training, consultancy or even interim-management by foreign partners. Language barriers may turn out to be a challenge, as well as the willingness of hospitals to allocate budget for these services.
3. Because of the size of its population and the relatively low access to well-trained doctors, e-health and telemedicine solutions are believed to be a great opportunity in China. This would enable distant patient monitoring and diagnosis, as well as online consultation. A challenge in this regard is to adapt the way doctors and healthcare institutions are organised to this new environment. Another issue is to enhance interoperability beyond the local level. Finally, it will be a challenge to find a profitable business model, as these types of communication services are not yet reimbursed.
4. Currently, the Chinese government is strongly boosting the rehabilitation sector, almost doubling the number of rehabilitation facilities by 2015. A Dutch consortium of rehabilitation knowledge institutions and companies may provide opportunity to provide local governments with integrated projects.
5. The ageing population causes for a huge demand of elderly care solutions. These can be nursing homes, but also community and home care solutions. In general, China is urgently looking for concepts that will work in the Chinese situation, and shows a great openness to learn from foreign experience. A challenge is the lack of long-term care insurance as well as the lack of standardization, which makes the business model for elderly care still underdeveloped.

6.2 ENTERING THE CHINESE MARKET

Depending on the specific profile of a company, entry of the Chinese health-care market requires tailor-made entry strategies. There is no 'one-size-fits-all' approach, given the complexity of policies on each market segment, the variety of decision makers and end-users, and the variety of products. Visiting China oneself is the best way to explore concrete possibilities on the market, as well as to have a first impression of the country, people, and culture. Meeting relevant partners is an essential part of the visit, whether the goal is R&D collaboration, start-up of a joint venture, technology transfer, or marketing and sales. Since potential Chinese clients may prefer to be offered a full package of services and products, it mostly is beneficial to approach the Chinese market in the form of business consortia. The Dutch government agencies mentioned in the next paragraph are often involved in the organisation of these missions.

Visiting China is the best way to explore concrete possibilities on the market

In addition to delegations, which are only focused on the industry, Dutch government officials also visit China, often accompanied by relevant organisations and companies.

After the first visits to China, much time and effort need to be invested in follow-up of the contacts. Doing business with Chinese partners means a long-term relationship in which trust is essential. The long-term investments in the Chinese market are also a consequence of the SFDA registration procedures, which are time-consuming and can take up to several years.

6.3 SUPPORT BY THE DUTCH GOVERNMENT

The Chinese LSH market has proven to have high growth potential, and it is expected that this sector will continue to expand. If you are considering entering this market or further developing your business, then several departments of the Dutch government can provide support:

- The Dutch Ministry of Health, Welfare and Sports (VWS) has stationed a Health Counselor in Beijing, who maintains G2G contacts (e.g. with MoH and SFDA), has an extensive network in national level Chinese institutions in the medical sector and in-depth knowledge of healthcare regulations and trends.

- The economic departments of the Dutch Embassy and Consulates in Shanghai and Guangzhou support Dutch companies, which are interested in entering the Chinese market, by providing general advice, troubleshooting, and business partner scans.
- Supporting Dutch business in economically important regions in China, the Netherlands Business Support Offices (NBSO's) are operating in Dalian, Chengdu, Qingdao, Jinan, Nanjing and Wuhan, among which NBSO Nanjing is the focal NBSO for the LSH sector.
- NOST (Dutch: Innovatie Attaché Netwerk) monitors the innovation development in China, can provide a general overview of technological trends and R&D companies and helps companies and research organisations to find potential partners. NOST offices are located in Beijing, Shanghai and Guangzhou.
- The Expert Center International Research & Innovation (EiOI) of Agency NL organises technology matchmaking missions abroad, and also provides advises for the application of European research funding programs such as KP7. The KP7 program is an initiative of the European Commission to improve the science and technology base and competitiveness of member states.
- The Health Counselor, economic departments, NBSO's and NOST in China have formed a Life Sciences and Health cluster, and work closely together to keep an up-to-date overview of China's healthcare market in order to provide Dutch companies with relevant information and tailor-made services.

7.

REGIONAL OPPORTUNITIES

Province	Description of life sciences industry
<p>Beijing Embassy of the Kingdom of the Netherlands in Beijing</p>	<p>Healthcare system: Beijing invests heavily in its healthcare system. The total healthcare expenditure reached 97.7 billion RMB in 2011, representing 6% of Beijing's GDP. The healthcare resources in level 3 hospitals are extremely stretched due to rapidly growing residential population and huge number of patients from outside of Beijing. To release the pressure on major hospitals and to balance healthcare resources between city centre and suburbs, the city's Public Health 12th Five-Year-Plan (2011-2015) emphasizes strict control on the expansion of hospitals inside the city. Meanwhile, the municipality will accelerate the construction of nine new hospitals outside the 5th ring road. These new hospitals are all affiliated to major level 3 hospitals to take advantage of their high quality medical care resources. At district level, Chaoyang and Shunyi districts have plans to build new hospitals for their large-scale residential areas such as Tiantongyuan and Huilongguan. Shunyi district plans to open four level 3 hospitals between 2011-2020. Chaoyang district will build four level 3 hospitals and expend or move seven level 2 hospitals between 2011-2015. These construction and expansion plans, as well as the ambition to equip new hospitals with advanced facilities and devices, present huge potential business opportunities for medical equipment and devices providers.</p> <p>Ageing: The population of 60-years and beyond reached 2.48 million in 2011. Beijing city adopted a "90-6-4" approach, with an aim that by 2020, 90% of the seniors live with their families, 6% receive home care service provided by communities and reimbursed by government and 4% live in elderly care institutions. The shortage of beds in elderly care facilities becomes more and more visible and attracts increasing media attention. The city is exploring solutions to cope with the challenge. Dutch experience and expertise in elder care, including technology-driven home care systems, can be a valuable reference to the city and starting point for concrete cooperation.</p>

<p>Beijing Embassy of the Kingdom of the Netherlands in Beijing</p>	<p>Rehabilitation: The city's health 12th Five-Year Plan recognizes the need of enhancing rehabilitation services. It sets up a goal to have 9806 beds (0.5 bed per thousand people) in public rehabilitation institutions by the end of 2015. In September 2012, Beijing opened its first municipal level 3 rehabilitation hospital: Beijing Xiaotang Mountain Rehabilitation Hospital. According to instructions of Ministry of Health, every level 2 and above hospitals must have a rehabilitation department by 2016.</p> <p>Biomedical industry: Beijing hosts three Life Sciences parks, such as Zhongguancun Life Sciences park. There are five National Engineering Research Centers and national top universities such as Peking University, Tsinghua, China Academy of Medical Sciences. Also, Beijing is host to many CRO's, three of which have FDA GLP approval. Companies in the Beijing area are leading in digital diagnostic and treatment devices. They represent 1/3 of the China market in diagnostic reagents, 20% of vaccines, 10% of Traditional Chinese Medicine and 1/3 of R&D Outsourcing. Multinational companies such as GSK, GE, Sanofi-Aventis, Novartis, Bayer and Novo Nordisk have set up an R&D center in Beijing.</p>
<p>Shanghai CG Shanghai</p>	<p>Shanghai is in the forefront of developing the healthcare sector. A few areas offer particularly interesting opportunities for Dutch companies:</p> <p>Elderly care/ageing: There are 3.5 million people of 60-years and older, living in Shanghai, amounting to 24.5% of the total population. As the traditional system of elderly care (children taking care of their parents) is no longer feasible due to the one child policy, the city has adopted a 90-7-3 approach: 90% of the city's seniors live with their families (home care system); 7% utilize community centers; and 3% pay privately to live in retirement communities. Local authorities are still looking for ways to shape the system of care for the 90% and the Dutch system of Thuiszorg could very well fit the Chinese context. For the other groups, large-scale building projects are being executed. As per spring 2012, foreign investment is allowed in the top end part (the 3%) of the elderly care sector in Pudong district. There are some high-end projects in Shanghai seeking foreign cooperation, most notably Chongming Island's 'Dongtan Project'.</p>

<p>Shanghai CG Shanghai</p>	<p>Rehabilitation: The Shanghai Medical Reform Plan and the city's 12th Five-Year Plan emphasize strengthening the rehabilitation medical configuration. Rehabilitation covers a much wider group of all ages (from cerebral palsy in kids to hemiplegia in elderly). In November 2012, Shanghai opened its first Rehabilitation Hospital. Nevertheless, there is still a lack of specialized doctors and nursing staff, as well as capacity.</p> <p>Medical devices: With the ambitious plan to improve access to care, the demand for medical devices in the new clinics will grow accordingly. Also, the market for semi-medical devices and other health- and home care products is considerable.</p> <p>Training: Making healthcare more accessible to the population requires not only hardware, but most of all it requires sufficient trained professionals to operate the hardware, run hospitals and provide care to patients. The Shanghai authorities have indicated interest in exchange/training programs in the following areas: Hospital management, Disease control (incl. AIDS prevention) and management of infectious diseases, Cancer management, GP training and primary healthcare (Shanghai is one of the first cities to pilot a GP project, a medical specialty unfamiliar to China before 2011).</p> <p>In general, the Shanghai authorities are most interested to meet clusters of companies that can provide a full package: architects, manufacturers of medical equipment, training etc.</p>
<p>Guangdong Province CG Guangzhou</p>	<p>Guangdong is one of the most prosperous provinces in China. Therefore, the people pay more attention to and are more willing to spend money on health. At the same time, Guangdong is facing great health challenges due to many factors such as rapid urbanization (60% in 2010 and 70% by 2015) and mass population movements.</p> <p>Some of the targets set by the Guangdong health authorities are: health indexes reach the levels of moderately developed countries by 2020; the average life expectancy reaches 76.8 by 2015; every 1000 people have 0.2 general medical practitioners by 2015; the three basic medical insurance schemes cover 98% of the population and reimburse over 70% of the medical fees by 2015; and 70% of the population will have their electronic medical records by 2015.</p>

<p>Guangdong Province CG Guangzhou</p>	<p>R&D: The Guangzhou Institute of Pharmaceutical Industry is the only institute in South China to get accreditation from both International AAALAC and National GLP. The research community in Guangdong is very interested in cooperation with foreign companies and institutes. Examples of cooperation between the Dutch and Guangdong R&D communities are a demo lab established together by Applikon Biotechnology and the School of Biological Science and Engineering of South China University of Technology in November 2012, and a collaboration project between Leiden University Medical Center and Guangzhou Institute of Biomedicine and health.</p> <p>Health reform: From 2008 to 2011, the total investment from the Guangdong government was 78.1 billion RMB (EUR 9.64 billion), with an annual growth rate of 28%. In October of 2011, the urban basic medical insurance schemes and the new rural cooperative medical scheme covered 96% of Guangdong population.</p> <p>NCDs: According to the World Health Organisation, main factors contributing to NCDs are alcohol consumption, tobacco use, unhealthy diet, and physical inactivity. In Guangdong, over 750,000 people drink excessive alcohol, 4.6 million adults smoke, 70% of the families take in too much salt, and only 20% of the population exercise regularly. Common NCDs in Guangdong are cardiovascular disease, diabetes, cancer and respiratory diseases, and chronic diseases contribute to 85% of Guangdong's deaths.</p> <p>Major life science clusters in Guangdong: Guangzhou Science City, Guangzhou International Biological Island, Baiyun District Biomedical Health Industry, Panyu Biological Industry Base, Conghua Biological Medicine Base, and Shenzhen Hi-tech Industrial Park, National Health Technology Park in Zhongshan.</p>
<p>Hong Kong CG Hong Kong</p>	<p>Hong Kong has a high standard of healthcare quality. Hospitals in Hong Kong are managed privately or by the government's Hospital Authority (HA). There are 12 private hospitals in Hong Kong, with over 3,500 beds; these are all members of the Hong Kong Private Hospitals Association. The HA manages 41 public hospitals and institutions, 48 Specialist Out-patient Clinics and 74 General Out-patient Clinics. According to the locations, services have been organised into seven hospital clusters. Total number of hospital beds is approx. 35,000. In the coming years, 4 new private hospitals will be gradually built to cater for the population in the new towns; an estimated total of 1,500 – 2,000 beds with a mix of medical specialties will be available to meet patients' needs.</p>

Hong Kong
CG Hong Kong

Medical & Healthcare Equipment: Hong Kong has two distinct markets: consumer market and institutional market. Medical equipment is sold mainly to hospitals and clinics, while healthcare equipment is mostly distributed to department stores via local distributors or local brand owner offices. Some bigger brands have set up their own specialty stores. The growth of the home healthcare equipment market is expecting a more rapid growth.

Pharmaceuticals: Due to ageing population, treatments for cardiopulmonary disease, diabetes and neurological disorders will anticipate a rapid growth, so as orthopaedic devices and pharmaceuticals that can help delay ageing. For pharmaceuticals entering into the Hong Kong market, government registrations and regulations are applicable.

Research & Development: There are two medical universities in Hong Kong (Chinese University and Hong Kong University) affiliated with two medical centres (Prince Wales Hospital and Queen Mary Hospital resp.). Both universities excel in many areas of medical research and have gained international recognition. Hong Kong has achieved breakthroughs in the recent years covering areas of computer navigation surgery, liver diseases, orthopaedic, prenatal diagnosis, leukaemia treatment etc. In addition, the HKU is globally the second highest cited institution for research on avian influenza and is one of the WHO's eight H5N1 reference laboratories. In 2010, the Hong Kong Institute of Biotechnology was established to strengthen Hong Kong's biotechnology industry while the advancement of Chinese Traditional Medicines (TCM) has been substantial in the recent years. The autonomous legal system and IPR protection make Hong Kong an ideal place for medical related R&D activities.

Prospect: Owing to the high standard of healthcare and modern society, there are opportunities for introducing more telemedicine and mHealth related technologies to the market. The government is pushing for healthcare reform and currently a territory-wide patient-oriented electronic health record (eHR) has been implemented on voluntary participation. Hong Kong would be open for more combined technologies which will enhance efficacy in healthcare.

<p>Hubei Province NBSO Wuhan</p>	<p>Hubei Province has listed the Bio sector as a strategic industry, focused on bio-pharmacy, bio-engineering, bio-agriculture. The province aims to achieve an annual output value of RMB 130 billion in the sector by 2015.</p> <p>Hubei has a leading position in China in the following areas:</p> <ol style="list-style-type: none"> 1. Fundamental research in general virology (represented by CAS Wuhan Institute of Virology); 2. Microbiology & immunology (represented by Wuhan Institute of Biological Products) 3. API synthetic pharmacy (represented by a number of local pharmaceutical companies) 4. Pharmaceutical and medical device logistics (represented by Jointown) <p>Biolake is a national Bio Industry Park located in Wuhan. A bio industry chain is being established in the cluster, ranging from R&D to production and services. So far, 500 companies have set up an establishment, with a total revenue of RMB 50 billion. Wuhan expects this figure to quadruple by 2018.</p>
<p>Jiangsu Province NBSO Nanjing</p>	<p>General info: Jiangsu has a population of 79 million (2011), with a density of 770 persons per km² (495 in the Netherlands). The average life expectancy in Jiangsu is 75,3 years. There are 31,680 health institutions in the whole province with 296,390 hospital beds. There are 481,181 personnel working in the sector, of which 134,683 are doctors. According to the Chinese Ministry of Human Resources and Social Security, as one of the eight municipalities and provinces, full coverage of medical insurance system has been achieved in both urban and rural areas. Jiangsu has formed a complete industrial chain including preclinical studies, clinical trials, pharmaceutical manufacturing operations, logistics and distribution. Some major industrial zones are China (Taizhou) Medical City and medical industrial zones in Suzhou, Wuxi and Changzhou.</p> <p>Government plans: Speed up the establishment of pharmaceutical industrial parks in Nanjing, Lianyungang, Suzhou, Wuxi and Changzhou, and upgrade the structure of China Medical City in Taizhou. Optimize the structure of chemical medicines, improve the drug products quality and grades, promote the modernization of traditional Chinese medicine, promote the industrialization of modern bio-pharma technologies and develop new medical devices.</p>

<p>Jiangsu Province NBSO Nanjing</p>	<p>Research & Development: Jiangsu has more than 800 research institutions, four Drug Safety Evaluation Centers accredited by the National Non-Clinical Trials Quality Management Practices (GLP), 30 drug clinical testing bodies certified by the National Drug Clinical Trials Quality Management Practice (GCP), 457 pharmaceutical production enterprises, 1951 medical equipment manufacturing enterprises, 549 pharmaceutical wholesale and retail chains, and more than 22,000 retail pharmacies.</p> <p>Until October 2012, 12,723 varieties of drugs have been approved by the state, which ranked 2nd in the country. According to the species, 32 A-Class drugs have been approved by the state, accounting for about one-third of the national total. In addition, with the sustainable industrial and commercial development of pharmaceutical industry, new industries like pharmaceutical R&D service outsourcing, modern medical logistics have strongly been upgraded in Jiangsu.</p> <p>Foreign involvement: There are 119 foreign invested enterprises in Jiangsu in the field of medicine production and 121 in the field of medical equipment production. The technologies of producing Soft IOL and Arteriovenous Catheter are in a leading position in China. Over the last decade, a number of Fortune 500 multinational pharmaceutical companies, like Pfizer, Novartis, GlaxoSmithKline, AstraZeneca, Bayer, Eli Lilly, etc. have built factories in Jiangsu. Glaxo invested 230 million USD in Suzhou Industrial Park, the largest investment of the group in China. Suzhou, Wuxi, Taizhou and Nanjing have increasingly become the main gathering areas for foreign investment in pharmaceutical industry. In Suzhou, for example, the sales revenue of foreign funded enterprises has accounted for more than half of the city's pharmaceutical industry sales revenue.</p>
<p>Liaoning Province NBSO Dalian</p>	<p>Medical industry: In 2011 in Liaoning, the production value of the medical industry was 55 billion RMB, and the sales revenue was 59 billion RMB. The medical industry is divided into four sub-sectors: The Chemical Medicine Industry, The Chinese Patent Medicine Industry, The Biological and Biochemical Medicine Industry, and the Medical Appliances Industry.</p> <p>The production value of the Chemical Medicine Industry was 23 billion RMB in 2011. There are about 100 companies in this industry. Leading pharmaceutical companies in Liaoning are the Northeast Pharmaceutical Group (vitamins, antibiotics, etc.); The Pfizer Dalian Plant (anti-infection, cardiovascular drugs, nervous system drugs and arthritis drugs, etc.); Astellas Pharmaceutical Shenyang Plant (anti-infection drugs, urology & dermatology drugs, etc.).</p>

<p>Liaoning Province NBSO Dalian</p>	<p>The production value of the Chinese Patent Medicine Industry was 5 billion RMB in 2011. There are about 60 companies in this industry, with as leading companies: Shenyang Hongyao, Liaoning Herbapax and Shenyang Shuangding.</p> <p>The sales revenue of the Biological and Biochemical Medicine Industry was 6 billion RMB. There are about 40 companies in this industry, and the leading companies are Liaoning Chengda, Liaoning Nuokang, Jinzhou Aohong.</p> <p>The sales revenue of the Medical Appliances Industry was 7 billion RMB. There are five large companies produce medical appliances. Three of them are in Dalian and are Japanese owned enterprises: Dalian Omron Co., Ltd (blood pressure monitors, digital thermometers, body composition monitors, pedometers, blood pressure monitors, non-invasive vascular monitors, etc.); Dalian Toshiba Co., Ltd (CT systems, x-ray systems, etc); Dalian JMS Co., Ltd (disposable hemodialysis tubing set, disposable syringe, disposable infusion set, etc.). Shenyang Neusoft Group (CT systems, MRI systems, x-ray systems, ultrasound scanner series etc.); Shenyang Shenda Endoscope Co., Ltd (endoscopes, operating instruments, etc).</p> <p>Liaoning Benxi Life Science Industrial Zone: approved by Liaoning NDRC as a provincial level industrial zone in 2008, and in 2010 approved by Ministry of Science and Technology to become the National Benxi Life Science Industrial Zone. So far about 14 billion RMB has been invested in the zone.</p>
<p>Sichuan Province NBSO Chengdu</p>	<p>Healthcare sector: The province (pop: > 80 mln) traditionally is a strong industrial base for China's bio-pharmaceutical sector and has listed the pharmaceutical industry as one of its focus areas. The provincial output is going up fast and ranks seventh nationally. A lot of research is carried out in the development of Traditional Chinese Medicine, with several national bio-tech research centers taking the lead.</p> <p>Chengdu as main area: Most interesting area for Life Sciences related companies is the provincial capital Chengdu (pop. > 14 mln). Cooperation with Dutch companies and organisations is welcomed by the municipal government, as explicitly stated by Chengdu Mayor Ge, during a meeting in 2012. The principal development trends and investment promotion fields in the healthcare sector of Chengdu are internationalization of medical centers, traditional Chinese medicine industry, medical rehabilitation, management & education of people's health, medical support platform, informatization of the healthcare industry and exhibition activities.</p>

<p>Sichuan Province NBSO Chengdu</p>	<p>Tianfu Life Sciences Park: For domestic and overseas companies that want to cash in the booming biomedicine industry in Chengdu, the Tianfu Life Sciences Park (220,000m² floor space) is among the top locations to start business. The park is part of the Chengdu High-Tech Industrial Zone, and it has a focus on research and development of biomedicines. It can accommodate enterprises of all sizes as well as R&D facilities and production bases funded by investors from around the world. To date, more than 40 enterprises with more than 1,000 employees have settled in the park.</p> <p>Chengdu International Medical Town: This area in the district of Wenjiang (NW of Chengdu) is one of the ambitious projects highlighted in the Chengdu City Development Plan for the Healthcare Industry (2010-2015). The project covers an area of 31.5 km² and involves a gross investment of RMB 35 billion. The park is designed to accommodate healthcare, health tourism and healthcare business, eg. preventive care, advanced therapy, medical education and comprehensive rehabilitation services.</p>
<p>Shandong Province NBSO Qingdao/Jinan</p>	<p>Healthcare in Shandong: Shandong is the second populous province in China, with a population of over 96 million (2011). In 2011, there were 68,275 health institutions, including 3,135 scaled hospitals and numerous clinics for communities and rural areas in Shandong province. Around 98.7% of the urban residents and 99.6% of the rural residents are covered by social medical insurance and the New Rural Cooperative Medical Scheme (NRCMS).</p> <p>Plans Shandong government: In the first half year of 2012, expenditure totalled 2.4 billion EUR, an increase of 25% compared to 2011. The average life expectancy in Shandong province is 76 years and the ageing population is growing fast. In 2011, the population of over 65 years old reached 9.43 million, accounting for 10% of total population, which will increase to 11.5 million and 11.7% by 2015. According to the 12th Five-Year Plan (2011-2015) of the province, the government will further enhance healthcare reform and innovation, intensify the total investment in the healthcare sector, and improve the public health service system for both urban and rural areas.</p> <p>Production in Shandong: the province is a main production base for pharmaceutical chemical materials, clinical medicines, medical devices and disinfection cabinets. The output of cephalosporin raw materials, disinfection cabinets and disposable medical consumables has been in leading position in China for many years.</p>

**Shandong
Province**
NBSO Qingdao/Jinan

Several large life science enterprises in China are located in Shandong province. For instance, Shinva Medical Instrument in Zibo (largest sterilizer R&D base and manufacturer of disinfection cabinets), Weigao Holding in Weihai (largest disposable medical consumable manufacturer and exporter), Shandong Xinhua Pharmaceutical Group in Zibo, is in close cooperation with DSM (one of the largest producers of cephalosporin raw materials). In addition, DSM has another two plants in Shandong to produce nutritional raw material and polymeric fibre.

Pharma R&D in Shandong: The R&D institutions for pharmaceutical industry in Shandong province include eight national level enterprise technical centers, two national level engineering laboratories, two national key laboratories, and 19 provincial level R&D centers (2010). Main pharmaceutical clusters in Shandong are Jinan Pharmacy Valley and Qingdao Blue Bio-medical Industrial Park.

Foot notes:

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- Netherlands Economic Network in China
- Provincial Capital
- PROVINCE NAME
- Provincial Border

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